Food and Drug Administration
Center for Drug Evaluation and Research

Endocrinologic and Metabolic Drugs Advisory Committee

Holiday Inn Bethesda
8120 Wisconsin Avenue, Bethesda, MD

Questions
July 27, 2001

NDA 21-318, Fortéo™ (teriparatide injection, rDNA origin) Eli Lilly and Company

EFFICACY

1. Based on the information presented by the sponsor in the NDA, are the data adequate to establish that teriparatide 20 ug/day is an effective dose

    a. for the treatment of postmenopausal osteoporosis to reduce fracture risk?
    b. to increase BMD in men with osteoporosis?

    If the answer to either of the above is no, what additional data would be required?

SAFETY

2. Based on the information presented by the sponsor in the NDA, are the data adequate to define the safety profile of teriparatide

    a. for the treatment of postmenopausal osteoporosis?
    b. for use to increase BMD in men with osteoporosis?

    Consider in particular with regard to duration of use.

    If the answer to either of the above is no, what additional data would be required?

APPROVABILITY

3. Based on the data presented by the sponsor in the NDA, do you recommend approval of teriparatide

    a. for the treatment of postmenopausal osteoporosis?
    b. to increase BMD in men with osteoporosis?

Consider in particular with regard to duration of use and appropriateness of teriparatide as first-line or second-line therapy for both indications.

If the answer to either of the above is no, what additional data would be required?

4. If the answer to either question in #3 is yes, given the theoretical risk for the development of osteosarcoma in humans treated with teriparatide:

   a. Should duration of treatment with teriparatide be limited? If yes, please comment on the recommended duration of use.
   b. Should use of teriparatide be recommended only for certain subgroups of patients? If yes, please comment on the recommended target population(s).
   c. Should teriparatide be limited to use as second line therapy? If yes, please comment on what criteria should be established to define second-line therapy.
   d. Please comment on how the osteosarcoma findings in rodents should be addressed in labeling (e.g., Bolded Warning, Black Boxed Warning).

POSTMARKETING/RISK MANAGEMENT

5. If the answer to either question in #3 is yes, please provide recommendations regarding strategies for postmarketing surveillance for the possible development of osteosarcoma in teriparatide-treated patients.

6. If the answer to either question in #3 is yes, what, if any, postmarketing studies do you recommend?